NC Medicaid and NC Health Choice
Pharmacy Prior Approval Request for
Sovaldi: Initial PA Form

Beneficiary Information

1. Beneficiary Last Name: _____ 2. First Name: _____
3. Beneficiary ID #: _____4. Beneficiary Date of Birth: _____ 5. Beneficiary Gender: _____

Prescriber Information

6. Prescribing Provider NPI #: _____
7. Requester Contact Information - Name: _____ Phone #: _____ Ext. _____

Drug Information

8. Drug Name: _____ 9. Strength: _____ 10. Quantity Per 30 Days:_____
11. Length of Therapy (in days): ☒ 8 Weeks (Do not change. Only 8 weeks can be approved with this form. You must use continuation form to request last 4 weeks)

Clinical Information

Total Length of Therapy (Check ONE):

☐ **12 weeks =** Genotype 1, 2, or 4 for treatment-naïve and treatment-experienced adult beneficiaries without cirrhosis or with compensated cirrhosis (child-pugh A); or genotype 2 for treatment-naïve and treatment-experienced pediatric patients, 3 years of age or older, without cirrhosis or with compensated cirrhosis (child-pugh A).
Genotype 1 and previously treated with a regimen containing an NS3/4A PI_2 without prior treatment with an NS5A inhibitor

☐ **24 weeks** = Genotype 1 adult beneficiaries that are PEG-interferon ineligible; genotype 3 for treatment-naïve and treatment experienced adults without cirrhosis or with compensated cirrhosis (child-pugh A); Or genotype 3 for treatment-naïve and treatment-experienced pediatric patients, 3 years of age or older, without cirrhosis or with compensated cirrhosis (child-pugh A)

☐ **48 weeks =** Genotype 1,2,3, or 4 for adult beneficiaries with a diagnosis of Hepatocellular Carcinoma awaiting liver transplantation (up to 48 weeks or until liver transplantation, whichever comes first)

1. Does the beneficiary have a diagnosis of chronic hepatitis C infections with one of the following confirmed diagnosis':
   ☐ Genotype 1 or 4 without cirrhosis or with compensated cirrhosis and beneficiary is 18years of age or older
   ☐ Genotype 2 or 3 without cirrhosis or with compensated cirrhosis and beneficiary is 3 years of age or older
   ☐ Beneficiary has CHC infection with hepatocellular carcinoma awaiting liver transplant
2. Are medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype being submitted with this request? ☐ **Yes** ☐ **No** ****Lab test results MUST be attached to the PA to be approved.****
3. Which of the following are included with the submitted medical records to document the staging of liver disease?
   ☐ Metavir scores ☐ FibroSure score ☐ IASL scores ☐ Batts-Ludwig scores
   ☐ Fibroscan score ☐ Ishak scores ☐ APRI scores ☐ Radiological imaging consistent with cirrhosis
   ☐ Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician
4. Does the beneficiary have a documented quantitative HCV RNA at baseline that was tested within the past 6 months (medical documentation required)? ☐ **Yes** ☐ **No HCN RNA (IU/ml): _____ and/or log10 value: _____**
5. A commitment to abstinence from alcohol and IV drug use is required. For beneficiaries with a recent history of alcohol abuse or IV drug use (within the past year), enrollment in a treatment program and/or counseling, and/or an active support group is also required. Beneficiaries must agree to toxicology and/or alcohol screens as needed. Does the beneficiary have a history of alcohol abuse or IV drug use?
   ☐ **Yes** ☐ **No**
6. As the provider, are you reasonably certain that treatment will improve the beneficiary's overall health status?
   ☐ **Yes** ☐ **No**
7. Do you attest that the beneficiary has been evaluated for readiness for treatment and the beneficiary agrees to be compliant

with therapy, follow-up appointments and labs? ☐ **Yes** ☐ **No**

8. Is Sovaldi being prescribed in combination with ribavirin and pegylated interferon alfa for genotypes 1 and 4? ☐ **Yes** ☐ **No**
9. Is Sovaldi being prescribed in combination with ribavirin for beneficiaries with genotype 1 who are peginterferon-ineligible (medical record documentation of previous peginterferon therapy or reason for ineligibility must be submitted for review)? ☐ **Yes** ☐ **No**
10. Is Sovaldi being prescribed in combination with ribavirin for genotypes 2 and 3 and/or in CHC beneficiaries with hepatocellular carcinoma awaiting liver transplant? ☐ **Yes** ☐ **No**
11. Is Sovaldi being used as monotherapy? ☐ **Yes** ☐ **No**
12. Is Sovaldi being used with any other sofosvuvir containing regimen? ☐ **Yes** ☐ **No**
13. Does the beneficiary have any FDA labeled contraindications to sofosbuvir (Sovaldi)? ☐ **Yes** ☐ **No**
14. Is the Beneficiary pregnant? ☐ **Yes** ☐ **No**
15. Does the beneficiary have severe renal impairment (CrCl less than 30 mL/min), end stage renal disease, or require dialysis (AASLD/IDSA 2014)? ☐ **Yes** ☐ **No**
16. Is the beneficiary a non-responder to sofosbuvir? ☐ **Yes** ☐ **No**
17. Has the beneficiary previously failed therapy with a treatment regimen that included sofosbuvir? ☐ **Yes** ☐ **No**
18. Does the beneficiary have hepatocellular carcinoma and is not awaiting a liver transplant? ☐ **Yes** ☐ **No**

Signature of Prescriber: _____ Date: _____

(Prescriber Signature Mandatory)

I certify that the information provided is accurate and complete to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.